Pages 1 - 85

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE ARACELI MARTÍNEZ-OLGUÍN, JUDGE

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,	)	
Plaintiff,	)	
VS.	)	NO. 21-cv-03496-VC-AMO
INTUITIVE SURGICAL, INC.,	)	
Defendant.	)	
IN RE DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	)	NO. 21-cv-03825-AMO-LB

San Francisco, California
Thursday, September 7, 2023

TRANSCRIPT OF PROCEEDINGS

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Official Reporter, U.S. District Court

(Appearances continued, next page)

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Thursday, September 7, 2023 **2:04 p.m.**

P R O C E E D I N G S

THE COURTROOM DEPUTY: Calling Case No. 21-cv-3496 and 21-cv-3825, Surgical Instrument Service Company, Incorporated v. Intuitive Surgical, Incorporated, and In Re Da Vinci Surgical Robot Antitrust Litigation.

Counsel, please come up to the podiums to state your appearances for the record, starting with the plaintiffs.

THE COURT: Counsel, if you will give me just a moment, please feel free to come to the lecterns. It's not my usual courtroom, so I'm taking just a minute to put everything where I need it.

MR. CORRIGAN: Good afternoon, Your Honor. Jeff Corrigan for the hospital plaintiffs.

MR. MCCAULLEY: Good afternoon, Your Honor. Richard McCaulley on behalf of SIS.

THE COURT: Good afternoon.

MR. BATEMAN: Good afternoon, Your Honor. Chris Bateman for the hospital plaintiffs.

MS. WINNER: Good morning, Your Honor. Sonya Winner for defendant Intuitive. And I have with me my colleagues, Ashley Bass, Andrew Lazerow, and Kate Cahoy.

THE COURT: All right. Counsel -- again, getting everything situated. Can we recess for a moment?

THE COURTROOM DEPUTY: Yes. The Court is now in

recess.

(A pause in the proceedings)

THE COURTROOM DEPUTY: Be seated. Court is back in session.

THE COURT: Okay. Now that we have had our false start, and also, before we get started, I just wanted to start by asking you all -- and you are going to get these handed out to you -- I want to ask for some help with some of the evidence.

What we need from you all is some help locating certain things in the record. And what we specifically need are citations from -- for both the redacted and unredacted versions of things. So what we want from you all is the ECF docket number and the ECF page number.

In your demonstratives, the demonstrative from the hospital plaintiffs is a good start, that chart, but it doesn't have the ECF page numbers, which is what would help us tremendously. So you are going to get passed out to you, from Ms. Solorzano, a short list of things where we would appreciate these citations from you.

If some of you here want to work on it now, sure. No need, but I would like those things from you, if not tomorrow, no later than Monday, say, noon. So that's the first thing.

With that, I thank you all for having provided Ms. Solorzano a proposal about how to proceed in terms of the

argument. I think it makes sense, and should work fine.

So as I understand it, right, just to make sure we are all on the same page, we are going to spend about 90 minutes together this afternoon. Eighty of those will be on the motions for summary judgment. Ten on the *Daubert* -- on one particular *Daubert* motion. And as I understand it, right, it's 44 plaintiffs on the motion for summary judgment, 40 for defendant.

And then as relates to the *Daubert* motion, even though I think we have counsel assigned from each party, or from each set -- for each of the plaintiffs and for the defendant for the *Daubert*, I have only -- I believe that your proposal was only for the hospital plaintiffs, so for defendant to speak. And I see some of you all nodding along.

So, assuming that no one has different thoughts about how we will proceed this afternoon, we'll just go ahead and start there. Okay. Please, come on up.

MR. CORRIGAN: Your Honor, before I get started, I just wanted to let you know, we've broken it down -- we're going to do 20 minutes hospital plaintiffs, five minutes SIS. Then I've reserved ten minutes hospital plaintiffs on rebuttal, and SIS has reserved five. That will comprise our 40.

THE COURT: And is someone keeping time for you?

MR. CORRIGAN: I think so, yes.

THE COURT: Let's pin that down just a little bit

more. Who is keeping time for you?

(A hand is raised)

MR. CORRIGAN: Mr. Spector.

THE COURT: Thank you. I appreciate that.

I saw you glance, I thought, at my CRD, and I'm like, oh, no, no.

MR. CORRIGAN: No, we got it, yes.

THE COURT: All right. Continue.

MR. CORRIGAN: Good afternoon, Your Honor. And welcome to the case. My name is Jeff Corrigan and I will be handing the summary judgment argument for the hospital plaintiffs, which does not mean that we ignored your standing order. We have four younger and less experienced attorneys who are prepared to handle the *Daubert* motions, and my colleague, Chris Bateman, will handle the Elhauge *Daubert* motion, later in this hearing.

As you know, I'll be using a PowerPoint today. And I thought you'd appreciate I came in comfortably under 206 slides. That being said, I know you've read the briefs, and I won't attempt to regurgitate them, but I'm just going to tell you our story, and try to hit some high points along the way.

THE COURT: Does anyone not know the story of the 206-page PowerPoint?

MR. CORRIGAN: My side does. I told them.

THE COURT: All right. Short version, someone handed

me 206 pages showing up for nothing this complex. So, they got a stern talking-to.

MR. CORRIGAN: I made a mental note, Judge: Less than 206. See, I'm pretty sharp that way.

So Your Honor, defendants, as a matter of routine, generally file summary-judgment motions as well as *Daubert* motions, but plaintiffs rarely do. As a matter of fact, this is my first summary-judgment motion I've filed in 23 years on the civil side.

(Document displayed)

MR. CORRIGAN: And the reason, of course, is there were usually so many factual disputes it doesn't make sense. It's not that clear cut. But there are two issues in this case where it is that clear cut.

Oh.

THE COURT: If it doesn't advance, I will let you know that I have them on my iPad.

MR. CORRIGAN: Yes.

(Document displayed)

THE COURT: Oh, beautiful.

MR. CORRIGAN: All right. Your Honor, our first issue there is Intuitive has monopoly power in these separate markets. The minimally-invasive soft tissue -- MIST -- surgical robot, and the EndoWrist repair and replacement.

Now, I'm not going to say much about this issue, but I

have one slide on it which I think drives the point home. It's a series of quotes, all of which are contained in Professor Elhauge's reports, and all of which support his opinion that indeed, Intuitive is a monopoly -- a monopolist, and facing no competition.

(Document displayed)

MR. CORRIGAN: The first two quotes are from Intuitive, itself. They're calling Intuitive a monopoly.

The second two quotes are from neutral third parties. One is a surgeon, and one is an article.

(Reporter clarification)

MR. CORRIGAN: Sorry. One is an article. And they both refer to Intuitive as a monopoly as well.

The last click are three series -- series of three quotes, all from Intuitive, all of which are referring to the fact that Intuitive faces no competition. Including the gem that's the third from the bottom, Intuitive CFO Marshall Mohr, 9/20 (As read):

> "We are sitting at a point where competition isn't here yet."

So in September of 2020, for a company that's been in business since late 1990s, he's saying competition isn't here yet. Our case is that these people are right. Their case is that these people are wrong.

Their economic expert, his opinion that this company has

no market power, he has to ignore all these quotes. And he does. But who are you going to believe? This group (Indicating) that lives and works in this industry? Or their litigation consultant?

(Document displayed)

MR. CORRIGAN: The next issue that we filed on is the FDA issue. I'll spend most of my time on that.

The IRCs -- they're independent third parties -- would not have been blocked by FDA from competing in the EndoWrist repair and replacement market in the but-for world.

There is zero record evidence that the FDA would have blocked these IRCs in the but-for world. The same way they did not block them in the actual world.

That's why this neat visual here: IRCs were not blocked by FDA from competing in the EndoWrist repair and replacement market, in the actual world.

(Document displayed)

MR. CORRIGAN: Now, I want to spend a couple of minutes -- interestingly, both sides filed for summary judgment on the same issue. It's got to be somewhat unusual. So for a minute I'll play offense; then I'll play some defense. But here's kind of a summary of our case right here.

The alleged need for FDA clearance did not shut down IRCs. Here's the first point. FDA has never, never determined that 510(k) clearance was necessary. And I'll talk about that one a

little bit more in a minute.

Number two: Absent such an FDA determination, IRCs would have and did continue competing in the EndoWrist market.

Number three: IRCs, in fact, entered the market without such clearance, and were driven out by Intuitive's anti-competitive conduct, not by their lack of FDA clearance.

And number four: If FDA clearance were ultimately found to be necessary, IRCs could have obtained it in the but-for world. And in fact, Restore/Iconocare has already obtained FDA clearance.

Now I'll play defense -- and there are no questions of material fact on any of those issues.

Number two, I'm going to play a little defense here. This is why Intuitive cannot win its regulatory bar argument. To win that argument, Intuitive must show -- and there's some overlap here -- that the FDA would have blocked IRCs from the EndoWrist repair activities, absent 510(k) clearance.

Now, Intuitive has to show that 510(k) clearance was required. But, also, that the FDA would have blocked them, when there is no evidence in the record that would have happened. So that's what they have to show. However, the FDA did not block IRCs from their EndoWrist repair activities, absent a 510(k) clearance, in the actual world.

And even if they showed that 510(k) clearance is required, and that the FDA would have blocked them in the but-for world,

they still have to show that IRCs would not have obtained such 510(k) clearance in the but-for world.

But, Restore/Iconocare did obtain 510(k) clearance in the actual world. And they or other IRCs could have obtained it earlier, if it hadn't been futile in light of Intuitive's anti-competitive conduct.

So I told you I would talk a little bit more about number one, there. And here's number one: FDA has never determined that 510(k) clearance was necessary.

(Document displayed)

MR. CORRIGAN: And here's the famous July 22, 2022 email. And I highlight the title there. It's from a guy named Anthony Lee that worked at the FDA, and it's dated July 22, 2022. This is the last email in a chain between FDA employees and Rebotix about whether Rebotix needed 510(k) approval. And in some of the previous emails, Mr. Lee said he thought that Rebotix did need 510(k) appraisal.

So Rebotix pushed back and said: We want to appeal. We don't agree with that; we want to appeal.

So Mr. Lee then sends this letter, this email, on that date. And he's -- it's almost painful how sheepish this language is. This guy has to walk back what he's been talking about for a while here (As read):

"I used the term 'decision' in a manner that may have incorrectly implied that FDA had

made an official regulatory determination related to Rebotix."

But in fact, this decision did not bind the FDA. So if it doesn't bind the FDA, why would it bind the IRCs?

Not only that, but there's the punchline:

"That is why there is nothing for Rebotix to appeal at this time."

So Rebotix pushes back; there's nothing to appeal.

(Document displayed)

MR. CORRIGAN: Another piece of testimony here. This is from a deposition from a guy named Stan Hamilton, who was with Rebotix.

I was at the deposition. And Intuitive counsel walked Hamilton through all the previous emails in this chain. And I thought: Wonder what he's going to do when he gets to the July 22nd email. When he got there, he just punted. No further questions.

So me, of course, being the savvy, skilled litigator that I am, I put the email in front of him, and I said, "Mr. Hamilton, in your mind, what does this do to the other prior emails?" This is what he said.

(Document displayed)

MR. CORRIGAN:

"It negates anything that they were appearing to do with..."

(Reporter clarification)

MR. CORRIGAN: Oh, sorry.

"It negates anything that they were appearing to do with respect to a regulatory determination or regulatory enforcement, and that was made clear in the last meeting that the timing was before this, and that included some fairly high people in the FDA."

"He was saying a lot of things that then got walked back, and you can see the result."

So the way Intuitive handled this deposition is indicative of some of the poor -- some of the damaging facts. They just pretend it didn't exist. When you get to that point, just pretend it didn't exist.

(Document displayed)

MR. CORRIGAN: Now, Intuitive agreed, pre-litigation, that FDA did not require clearance to use EndoWrists. Matter of fact, multiple internal determination that FDA did not require 510(k) clearance to extend the uses or refurbish EndoWrists.

Their extended use program in August of 2020. They extended the lives on certain Xi EndoWrists.

And in their NFJ, which is a non-filing justification, sort of -- it's something they tell themselves as to why they don't have to file for 510(k)., (a) there (As read):

"Does not involve any changes to the intended use or the instrument design."

And the second one goes even further:

"The changes described in this non-filing justification do not require premarket notification submission before commercial distribution."

And the second decision they made internally when they did Project Dragon, which was their program to refurbish and reset instruments:

"Clearance/registration required: No."

So, two separate occasions several years apart, they determined internally, before this case started, that 510(k) clearance was not required.

Now, the FDA's refused to subject IRCs to remanufacturing requirements. One of the things we agree about with Intuitive is: The FDA's looked at this issue for years.

Now, did they forget about it? Why haven't they weighed in? Did they forget about it? Of course not. This has been a hot-button issue for 30 years. But, they still haven't subjected them to the 510(k) requirement. And, why?

And this is from our FDA expert. Essentially she says (As read):

"Requiring all non-OEM entities...to register as...remanufacturers and abide by relevant

regulations would substantially increase the cost to hospitals (and, ultimately, to patients) of reusable devices. And so, in spite of enormous pressure from OEM lobbying and OEM trade groups," -- like Intuitive -- "FDA has steadfastly refused to subject those service providers to remanufacturing requirements."

The second bullet is kind of more of the same: The FDA doesn't see any health problems, so why saddle them with all these costs? Another point in our brief, where the FDA describes these third parties as critical to the healthcare system.

And the third bullet is an interesting one. In 1998, the FDA revoked the guidance that required reconditioners and rebuilders to seek 510(k) clearance. And indicated further rulemaking was required. To this day, they have not put out that further rulemaking.

So for 30 years, they've sat on the sideline. Thirty years, and it goes on today.

THE COURT: Let me interrupt for just a moment.

MR. CORRIGAN: Sure.

THE COURT: I have a question here. And, you all will get a chance, as well. But, is your position that if the FDA takes no enforcement action, that means that that action is not

violating FDA regulations?

MR. CORRIGAN: No, not necessarily. I mean, they've looked at it for years, though. It's not that they don't know it exists. They've looked at it. The July 22 email says that. There's a number of emails leading up to that. So it's not that they just didn't take any enforcement. They punted, when it was right in their lap. So it's not just a question of enforcement or not.

They knew about it, and they haven't done anything about it. That's our point. They've sat on the sidelines not by accident, not by mistake.

But, you know, I just showed you the clip from our expert. They have sat on the sidelines, because there were no adverse events, there were no health problems. And therefore, they don't see the case for saddling them with extra costs on groups that are critical to the healthcare system.

Does that answer your question, Your Honor?

THE COURT: It does.

MR. CORRIGAN: Thank you.

So the last one there is the punchline:

> "Intuitive's request that this Court ignore FDA's caution and instead require 510(k) clearance MUST be rejected."

Now, we cite the *Nexus Pharmaceutical* case there, Your Honor, which is a 2022 case. And I'll give you one line

from that case which kind of lets you know where it's going (As read):

"We have been protective of FDA's statutory monopoly on enforcement authority."

So the Ninth Circuit in this case is saying: We stay out of it. If it's the FDA's purview, they do it first.

(Document displayed)

MR. CORRIGAN: Now, I'm going to play defense a little bit here. And this is from -- this is from Intuitive's brief. Okay? So, in order -- Intuitive says that we can't show -- (As read)

"Proximate causation of antitrust injury to these plaintiffs is lacking here for multiple reasons..."

And they cite three different reasons, and I'll take them one at a time. Number one -- this is the main one:

"...the governing regulatory scheme precluded the 'competition' through remanufacturing of EndoWrists that plaintiffs claim should have existed;"

Now I want to take a clip from their brief. Now, as you know, in the summary judgment brief you put your facts down. And then you pivot off the facts, and you make your legal arguments.

So here's a clip from their facts section (As read):

"Rebotix entered into a relationship with Restore..."

And I'll skip to the highlighted.

"Restore performed these functions for several months, but Rebotix terminated the contract in late 2019."

So here's where the IRCs stop. Stop working. And they cite Exhibit 20 there. But, Intuitive says nothing about the FDA stopping them. Right? And we'll see why.

Intuitive cites to their own Exhibit 20, and that's Glenn Papit's testimony. He was a Rebotix guy.

Papit says:

"We discontinued the relationship [with Restore] because of a lack of performance."

Well, what caused lack of performance? There's a clip from the Restore summary-judgment opinion there (As read):

"There is evidence...that this 'lack of performance' that led to the termination of the licensing agreement was a direct result of Intuitive's alleged anti-competitive conduct..."

So we're talking about Restore and Rebotix.

What did Restore and Rebotix do? They both sued Intuitive for shutting them down, they both survived summary judgment, and they settled their cases on the eve of trial.

And in connection with those settlements, those IRCs are free to continue repairing and resetting the EndoWrists. They didn't stop them. The settlement allows it to go forward.

THE COURT: Can I pause you there?

MR. CORRIGAN: Sure.

THE COURT: And this'll preview for you all a question that I would like answered by every party, which is why any of you think that I should reach a conclusion different than either of the District Courts in Florida, which essentially denied everyone's summary judgment, and made you all prepare for trial, which, of course, never happened.

But I would -- you know, I saw in the May 31st statement that I asked you all to file, the further case-management statement, a short explanation that you think that in your briefing you've given it to me for why the Florida cases aren't dispositive. But, I would appreciate it if today you could give it to me, sort of short and punchy, what Ninth Circuit precedent is -- I'm assuming that there's something different in the Ninth Circuit, as opposed to the Eleventh, that requires a different result.

So as long as we're bringing up the Florida cases, let me tell you --

MR. CORRIGAN: Sure. I'll be very short and punchy, Your Honor. Let me go back a little ways, to before you were on this case.

Intuitive filed a motion to stay in August of 2021. And Judge Chhabria denied that motion to stay, in one sentence. Okay? On Page -- it's Document No. 43, and on Page (ii), they said -- oh, sorry about that.

Intuitive says, and I quote:

"The resolution of those pending actions will necessarily address numerous identical fact and legal issues..."

THE COURT: I've got their -- I've got them on record. I'm curious why you think you are entitled to summary judgment. And I realize that the parties -- you represent the hospital plaintiffs.

MR. CORRIGAN: Yes.

THE COURT: So maybe you are differently situated then the folks there. But --

MR. CORRIGAN: Well, my question is your question: Are these courts wrong?

Now, here's (Indicating) one reason why they're not wrong. They did not cite either opinion in either brief. So they've made no attempt to show you that they're wrong, they've made no attempt to distinguish those cases, because they necessarily address numerous identical fact and legal issues.

So in those cases, the judges, as you know, denied summary judgment for Intuitive. And that's why they're not in the case.

But in the *Rebotix* case, okay, the *Rebotix* court said -- and I have the quote here somewhere -- okay. On Page -- I think it's Page 8, but I'll let you know shortly -- the Court there said: The FDA has not ruled. They have not made a final official ruling. So I'm not going to rule on summary judgment for Intuitive. But, the FDA could still make a ruling before the eve of trial. And if they don't -- if they do that, we'll deal with it.

But if the FDA does not make a final official ruling before the eve of trial, she invited Rebotix to renew their summary-judgment motion. And she said: I will grant it.

So she's saying a couple things there. One is she's saying that the FDA has not made a determination.

But, two, she's saying: If they don't come back in time that I rule, plaintiff is going to win.

Now, we have seen nothing. A lot of the citations in these opinions are from the Supreme Court. They both cite the *Zenith* case on the key issue in this case, which is their harm. How do you prove the harm.

So our position is that there was no -- there was no distinguishable. The facts are the same. The legal issues in Intuitive's own words are the same. And the result should be the same, except on this point where, if the FDA still has not -- and to take the mystery out of this, the FDA has still not -- the *Rebotix* opinion was August of 2022. The FDA has still

not spoken on this since July of 2022. At this point in time, the record is the same as stood before the ***Rebotix*** judge. So there should be no difference in the result.

That's our answer to that question, Your Honor. Is that sufficient? Or --

THE COURT: Yes.

MR. CORRIGAN: Okay, thank you.

THE COURT: Please proceed.

MR. CORRIGAN: So I'll breeze through this one pretty quickly. And it's -- again, they make the same argument. They say that Rebotix and SIS stopped working together, but they say nothing about the FDA stopping them.

They cite deposition testimony from the SIS exhibit, from the SIS president. He only talks about why -- what they were doing, not why they stopped. And of course, why they stopped was Intuitive shut them down.

So the first reason there, the main one, is meritless and should be rejected. All right?

Their second reason in their brief: These plaintiffs had no interest in using manufactured EndoWrists. That's a head-scratcher. When I saw that, I thought: Why would you say something, not just once, but multiple times in multiple briefs, that's so easily disproven?

Here's what I mean.

(Document displayed)

MR. CORRIGAN: Now, first of all, it doesn't even matter, right? Our damages analysis is that competition would have lowered prices for all plaintiffs. All plaintiffs. So that regardless of who is seeking the -- who wants to use the reset EndoWrists, doesn't matter.

Number two -- I'm going to skip number two because I have only a brief moment. All plaintiffs were interested in using repaired EndoWrists.

Now, here's Jose Gonzalez. He was the director of surgery at Larkin.

I got about a minute left.

MR. MCCAULLEY: You can have two of mine.

MR. CORRIGAN: Thanks, Rick.

He was the director of surgery at Larkin. Okay, Larkin Community Hospital. And I picked them because I worked with them for years. They're down there in Miami, doing God's work. They deal with prison population; they deal with nursing home population; they got a large percentage of Medicaid population. And they're always up against it, somehow.

So Mr. Gonzalez is the director of surgery. And he was the right-hand man to the CEO, who was Sandy Sosa-Guerrero. And his deposition, almost the entirety of it, was about their interactions with a company called Revanix, who is a distributor for Rebotix. He talked about his interactions. There were emails, there were price lists, there was testimony.

There was an in-person meeting.

Here's a clip from his testimony.

(Portion of audio recording played in open court, not reported)

MR. CORRIGAN: So there, he is talking about their interest in dealing with Revanix on resetting the instruments. So the second -- the second answer there is meritless and should be rejected.

And let me just talk about their third reason there (As read):

> "...insofar as plaintiffs' claims relate to Xi/X EndoWrists, no potential competitor has ever had the ability to re-set those devices."

There's another head-scratcher. That can be disproven with one snippet of deposition testimony. One snippet.

(Document displayed)

MR. CORRIGAN: And there it is. That's, again, Stan Hamilton. Right after the bolded (As read):

> "Are you saying that from a technical standpoint, Rebotix has actually reset the usage [counter] on an Xi EndoWrist instrument as of today?
>
> **"ANSWER:** ...I said yes."

(Reporter clarification)

MR. CORRIGAN: Not at all. There's the quote right there from Mr. Hamilton:

"QUESTION: Are you saying that from a technical standpoint, Rebotix has actually reset the usage [counter] of an Xi EndoWrist instrument as of today?

"ANSWER: ...I said yes."

So how would they say he doesn't have the ability; nobody had the ability?

I'll click through that one.

Therefore, the last reason is meritless, and should be rejected.

And that's all my time. Thank you, Your Honor.

THE COURT: While you all change up, I will not hold it against you if you speak more slowly so that Ms. Ball can keep up with you. So while I don't want -- while I don't want you all to think that means we are going to be here an extra half an hour, please --

MR. CORRIGAN: No, I was warned a couple times.

THE COURT: No, no, you're -- that's why I want -- I would like that to be the last time.

MR. CORRIGAN: (Inaudible)

THE COURT: So yes, please. If it -- don't -- there's no red light; I'm not going to turning off the mic. You may just initially get a stern look.

But, take a little extra time. It's fine.

MR. MCCAULLEY: Thank you, Your Honor. Mr. Corrigan owes me a few minutes, but we'll figure it out amongst ourselves. I just want to make a few points, briefly.

As Your Honor is aware I represent SIS. And we're a little bit different case. We are an IRC. We're the company that was involved in the process of resetting the counters for the hospitals. For our friends like the plaintiffs, and Larkin, and the other hospitals that are part of the purported class. I just want to touch on a few points that are a little bit different from our brief.

I join Mr. Corrigan in saying that we believe that the Florida courts got it right, for the reasons that he said. I'm not aware of anything in the Ninth Circuit law that's more restrictive that than Eleventh Circuit that would make a -- that would argue for a different result. So I think we're in the same spot, and we agree with everything that he said.

There's one issue that comes up in the briefing on our case about the change from a pin connection to an RFID chip for the Xi instrument. And much of the argument that is offered by the defendants relates to the fact that they say we haven't proven a less restrictive alternative.

I stand by our briefing on that point, that we have offered both technical and contractual provisions that could be less restrictive. For example, you could not threaten to shut

down somebody's robot if they used a reset counter on an EndoWrist.

But the one point that I think gets skipped over is whether or not, in the second prong of the analysis, the defendants have established that they had a non-pretextual pro-competitive reason for making that change.

And what we would have expected here, Your Honor, is to see a bunch of contemporaneous emails that talked about the benefits of making that change. We would have expected to see a bunch of internal discussions, documents, test reports, that led up to making that technical change in the Xi from the pin connection to the wireless. But we don't see any of that. And I think it's telling.

And I would invite the Court to look at the briefing and look at the evidence that they cite. They don't cite to contemporaneous documents; they cite to a couple of paragraphs in their expert report that talks about, you know, potential reasons that they might have made the change.

But what we would expect to see is what the Court referred to in the *Allied* case at Page 1001: Substantial contemporaneous documents at the time that the change was made in the product that told the compelling story about why they were making the change.

We've got three AmLaw 20 firms against us Your Honor. They've got all the information. They've got access to the

Intuitive employees; they've got access to all the email. We didn't see any of it. We didn't find it when we looked in the documents.

What we found is what we've attached as Exhibits 33 and 34 to the VanHoven declaration, which are contemporaneous emails from the engineers involved in the project in 2011, that said the reason that they were doing this is to keep people from reprogramming those EndoWrists.

They don't have any countervailing evidence to support their position. They have after-the-fact, fig-leaf-like concocted arguments to support a pro-competitive rationale for making the technical change in the EndoWrist.

I'd like to speak just briefly about the Lanham Act as well, because they -- and I'll go very quickly, and focus on their statements.

We've accused them of a Lanham Act violation, for the letters that they sent out. And they have come back and said: Well, that's a non-actionable opinion. But there's an exception to that rule, Your Honor, under Ninth Circuit law. It has to be a genuinely-held belief.

And I would refer to the slide that Mr. Corrigan showed up, his Slide No. 8, that talked about when they were looking -- "they" being Intuitive -- were looking internally at doing a similar type of project, they concluded FDA approval wasn't necessary. Yet, they went out with a scare tactic to the

industry, saying it was necessary.

So, Your Honor, we have at least a question of fact as to whether or not that was a genuinely-held belief, a genuinely-held opinion, or whether that was just a deceitful statement made to intimidate the market. And we're entitled to the jury on that.

The last point that I'll make is: That letter was signed by chief of regulatory and legal counsel. And to say that that's a lay opinion is belied by the fact of who they had sign the letter.

I tried to make it brief, and I tried to talk slowly. I'll reserve whatever time I have left for rebuttal.

Thank you, Your Honor.

THE COURT: Thank you, counsel.

MS. WINNER: Good afternoon, Your Honor.

THE COURT: Give me one second to get mine.

MS. WINNER: Sure.

THE COURT: That -- yeah.

Go ahead, Ms. Winner.

MS. WINNER: Thank you, Your Honor.

I do plan to respond briefly to what plaintiffs' counsel have said about their affirmative motion for summary judgment, although I think it was largely answered when counsel had to say: Who are you going to believe?

When you're asking that question, what you're basically

saying is that this is something for the jury, as to who is going to be believed on something.

But anyway, what I'd like to do is to start today with the first issue that's set out in our own motion for summary judgment. And that's the question of whether the alleged injury for which plaintiffs seek damages in this case can, as a matter of law, be treated as antitrust injury. If that issue is resolved in our favor, this issue should make it unnecessary for the Court to address the plaintiffs' motions.

Now, the plaintiffs' arguments in their briefs, and again, today, dance around the edges of antitrust injury. But they never really confront it. Our basic point is this: Plaintiffs cannot establish antitrust injury for their claims about EndoWrists, because none of the entities that were involved in modifying EndoWrists to bypass their use counters, including SIS, had a legal right to engage in that business without FDA clearance, which they did not have.

Now, plaintiffs' counsel spent a lot of time today on the issue of causation. What caused those companies to go out of business. But to state an antitrust claim, it is not enough for the plaintiff to show that it suffered injury that it claims was caused by the challenged conduct. It must also show, as an independent element of its burden of proof, that the injury is of a kind that the antitrust laws were intended to prevent.

For purposes of these motions, the issue of antitrust injury, distinct from causation, presents two questions. First: Can antitrust injury be shown, based on a plaintiff's inability to engage in a business that the law prohibits, either because the plaintiff doesn't have the necessary regulatory clearance, or for some other reason?

Second question, of course, is whether the activity in this case, the remanufacturing of used EndoWrists without FDA clearance, is a lawful one that can provide a basis for antitrust injury.

So let me start with the first question, which plaintiffs' counsel did not talk about. The overwhelming majority of the K courts (Phonetic) that have addressed the question have held that a plaintiff cannot rest a claim of antitrust injury on its inability to pursue business activities that are not permissible under an applicable regulatory regime.

THE COURT: I'm going to pause you for just a moment.

MS. WINNER: Sure.

THE COURT: Because -- well, that feels like the question on the table, though, right?

The one thing that you all seem to want is an ultimate resolution, look. And to my mind, the folks you really want to hear from is the FDA. And, unable to get them to take -- to give you a final answer, you've come to this district; you've come to the courts in Florida.

But I want to push you a little bit, because what I'm gathering the dispute is is ultimately whether the work that's being done by SIS is repair or remanufacturing. And, like, that feels like the million-dollar question, because that tells us whether what they're doing requires the 510 clearance -- 510(k) clearance, or not.

So I hear you very definitively saying that it was required, and I just want to push back on that.

MS. WINNER: Sure. And that's -- that is the big question here. Because I -- I don't think it is seriously disputed -- and I could spend more time talking about the cases; I don't think Your Honor needs it.

The cases are pretty clear that if it would be required -- they didn't have it; it's undisputed they didn't have it -- then they cannot prove antitrust injury. And again, that's different from causation.

You asked, by the way, about the Florida decisions. I think that's one of the reasons that neither side made much of the Florida decisions in our summary judgment papers. Although, we did actually cite it. I think it's in a footnote in our brief, but we did refer to them.

One of the reasons is they didn't really talk about -- they didn't go really on the issue of antitrust injury, so much as the question of causation. And they found that on causation, did the lack of FDA -- was the lack of FDA clearance

the cause of them going out of business, that that was a disputed issue of fact.

That's a different question from the question of whether operating without FDA clearance is something that could be a basis for antitrust injury. And in this district, and in the Ninth Circuit, the law is much stronger on that subject.

You asked about the Ninth Circuit versus the Eleventh Circuit. There really isn't -- I don't think there actually is any Eleventh Circuit case law on that.

There is a law on that in this circuit. There's numerous decisions from judges in this court, there's language in decisions of the Ninth Circuit, and of course, there are many decisions from other courts all across the country that, on the question of antitrust injury specifically, you know, support our position.

But let me get to Your Honor's question, which is: Did they -- did they need -- is remanufacturing EndoWrist without FDA clearance unlawful, and is that something that we can properly bring to Your Honor.

And, and let me just start with the law here. They -- they have offered a lot of discussion in their briefs about how mere service or mere repair of EndoWrists would not require endo- -- FDA clearance. And that's really a red herring, because that's not the question. The question is: Is this remanufacturing? There is a regulation on that, if we can put

it up.

(Document displayed)

MS. WINNER: We've cited this on our brief. There's a regulation that defines what remanufacturing is. And this is definitive from FDA; this is binding law.

Now, I want to start with what no -- in talking about this, what nobody disputes here.

First, plaintiffs do not dispute that if the modifications we're talking about constitute remanufacturing under this regulation, FDA clearance is required. No dispute about that. And we said it. We cite the regulations in our brief that establish that.

They argue that other kinds of activities that are not covered by this regulation don't require FDA clearance, but that's not the issue here.

Second, it's also undisputed that none of the would-be competitors who Intuitive is alleged to have stymied had FDA clearance for remanufacturing EndoWrists.

There's zero evidence in the record that Intuitive ever did anything to interfere with anybody's ability to get FDA clearance, or that anybody was deterred from seeking FDA clearance, as a result of anything Intuitive did.

In fact, Rebotix applied for FDA clearance back in 2015. They withdrew that application, but there's no suggestion in the record that it had anything to do with Intuitive. They

withdrew it because FDA found their application deficient, and said they were going to have to develop and provide a lot more expensive safety testing data in order to get clearance.

Then, Iconocare sought, and last year, actually obtained FDA clearance.

And just so that it was very clear, this was the first time -- when Iconocare got its clearance, that was the first time that ever happened. Intuitive immediately made public to everyone, very clear, that it had no objection to anybody using FDA-cleared remanufactured EndoWrists.

Intuitive's issue has always been -- and it's been very clear, including in the communication counsel was pointing you to a few minutes ago, it's been very clear that the issue is remanufacturing EndoWrists without FDA clearance.

The third thing, there's no factual dispute about what they were actually doing here. They were taking this very delicate surgical instrument. They were cracking it open, prying the top off it, taking a large piece of it out, prying a chip off a circuit board, soldering it onto a different circuit board that would have another extra component to it that they were adding so it could circumvent the use counter. Then putting everything back together again, and sending it out to be used on surgical patients. So there's no dispute about what they were doing.

So, back to the regulation. Again, there's no dispute,

this is -- this is the law. This regulation is the law (Indicating). And the plaintiffs' briefs offer virtually no discussion of how this regulatory language actually applies to what they were doing here. They didn't discuss it here today.

Instead, what they argue is that there was a general policy debate about -- and this was the quote on their slide from their expert -- whether all non-OEM entities who do anything have to have clearance.

Well, that's not what we're talking about. Non-OEM entities do a lot of things that don't require clearance. But when they do remanufacturing within the meaning of this regulation, clearance is required.

There's been a general policy debate about whether FDA should promulgate additional rules for entities that engage in reconditioning or servicing or repair that is not remanufacturing. FDA has not issued new regulations about that. But again, that's not the issue that is before Your Honor here today.

So let's look at the regulation. It says:

> "***Remanufacturer*** means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use."

The performance and safety specifications of an EndoWrist include a limit on the number of uses, for which there has been a full safety validation done, with extensive testing. There's no dispute in the record about what has actually been cleared by FDA for these devices.

The plaintiffs argue that the usage specifications for an EndoWrist are too strict. That the use limits are too low. And those are arguments they are perfectly entitled to make to FDA in a 510(k) application for clearance, so that they can add mod- -- add more uses through their modifications.

But that doesn't change the fact that the current use limits are what FDA has cleared. So further clearance is needed, if someone wants to modify an EndoWrist to ask more -- add more.

So let me talk about what FDA has said about this. And I'm also going to -- I'm going to circle back to what they say FDA has said. But let me start with the -- the undisputed record on what FDA has actually said.

(Document displayed)

MS. WINNER: Going back to 2015, FDA told Rebotix when it was issuing deficiency letter on its 510(k) submission, requiring more testing, this was in part because of the fact that the device that they were creating is not simply a reusable device, but it's a third-party reprocessed/remanufactured device.

So FDA back in 2015 was saying: This is a remanufactured device that you are creating here.

(Document displayed)

MS. WINNER: And this was in Exhibit 22.

In Exhibit 23, then, also in 2015, FDA told Rebotix, in no uncertain terms:

"You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug and Cosmetic Act."

In 2018, in response to an inquiry from a distributor for Rebotix, --

(Document displayed)

MS. WINNER: -- FDA said:

"...if the use-life counter is reset or extended past the number of available use lives, then the device specification are changed. As such, you would be considered a remanufacturer..."

Under the regulation.

(Document displayed)

MS. WINNER: Then in 2020, after looking at Restore's website and seeing what Restore was doing, FDA said:

"Based on this information, we believe that a

510(k) is needed before you continue your operation."

(Document displayed)

MS. WINNER: Exhibit 35, in 2021, an "It has come to our attention" letter -- which is a form of letter that experts on both sides agree is sort of the first step of an enforcement action -- was sent to Rebotix, saying:

"...the da Vinci S EndoWrist Instruments were cleared for a set number of uses."

Then, in the process of clearing Iconocare's 510(k) application, there was a requirement that FDA specifically imposed on Iconocare -- and this is Exhibit 41 -- saying:

"Since your device is considered a remanufactured device, please include the following on your device housing: 'Remanufactured By'..."

So they were required to put that right on the device that it was remanufactured.

(Document displayed)

MS. WINNER: And then in 2022 -- this is Exhibit 37 -- back to Rebotix (As read):

"We...request that Rebotix stop engaging in the current activities until an application is reviewed and cleared or granted."

Around the time that the Iconocare application was

applied, then, up on the website, the FDA website, they put up an official designation for -- what they call a "product code" -- for a remanufactured instrument -- surgical instrument for a computer-controlled system that has been remanufactured to extend its use life.

And this is Exhibit 1, Figure 3, is where this is in the record.

Now, you heard about -- there were two pieces of evidence that got cited on all of this by plaintiffs today. One is this email from Mr. Lee.

Now, Mr. Lee did not say: Oh, we've changed our mind.

Mr. Lee, in fact, if you saw the whole email -- it wasn't all on the slide -- would say: We're still encouraging them, actually, to file a 510(k) application.

What he was saying is this was -- this was not the kind of official appealable order that they -- that they could appeal at that point.

But FDA explained to them that they could get an appealable order that they could appeal, if they wanted to. They chose not to do that.

As for the Hamilton testimony that was cited to you, there's a snippet from that testimony. They didn't give you the whole thing.

We actually objected to this testimony in our reply brief, and we restate our objection now. It's -- it's just -- it was

responding to a question basically asking the witness what he thought was his impression of what FDA had in mind.

Insofar as it was purporting to offer unattributed hearsay from people he didn't identify, it wouldn't be admissible, on that ground. And it's certainly not admissible about his opinion about what FDA thought.

But, that's basically what they've got. FDA's actual statements about this have been consistent, over a period of years.

Now, to be sure, there has not been an enforcement action. There never needed to be one. That's the -- that's really the easy answer to that.

It warned -- FDA warned both Rebotix and Restore, repeatedly, that what they were doing required FDA clearance. It even went so far as to send that preliminary letter to Rebotix about it. But the remanufacturers, Rebotix and Restore, back down, and stopped what they were doing.

Now, we can go back and forth all day about why they made that decision. Maybe they were listening to FDA; maybe they were afraid of Intuitive. Whatever their reason was, the bottom line is they stopped, so there was nothing to enforce.

So this is not a situation where we have something that's sitting before FDA, FDA's pondering this, has been pondering it for years. FDA hasn't been pondering anything at all on this particular question. FDA has given the same clear answer to

the question every single time anybody has asked, and a lot of times when people tried not to ask.

These have been -- these may not have been formal regulations. The formal regulation is what I showed Your Honor earlier. That's on the books. That's the law. But these statements were made by FDA employees, in the course of their ordinary authority, within FDA. There's no suggestion in the record that any of these were unauthorized, off-the-reservation comments.

And so, you know, the enforcement issue really is a red herring. And for purposes of antitrust injury, it's irrelevant.

The *Pharmacychecker.com* case, the *Modesto Irrigation District* case, the cases that we cited on antitrust injury in our brief, those cases did not go off on there being enforcement action. They were based on the court looking at the law; determining that, under the law, the activity at issue was not lawful, in some cases, because required authorization was not provided or was not -- didn't -- the plaintiff didn't have the required authorization, and therefore, antitrust injury could not be shown.

The question of whether something constitutes antitrust injury, in other words, does not turn on whether the alleged injury was caused by enforcement action. It turns on the fact that the antitrust laws do not offer a remedy for an injury to

a business activity that the plaintiff did not have a legal right to pursue in the first place.

And I think Judge Patel's -- a discussion of this subject in *Modesto Irrigation District*, which was later affirmed by the Ninth Circuit, provides a very good explanation for why this is the case.

Now, I'm not going to spend time -- my time is also short, so I'm not going to spend time talking about the *Nexus Pharmaceuticals* case. The main thing I'd just say about that, it was not an antitrust case. It was not about -- it did not address the question of antitrust injury. And it certainly did not say that a Federal Court cannot ever decide any issue in a case under a different law by closing its eyes to what FDA regulations or the Food, Drug, and Cosmetic Act require.

To the contrary, there are plenty of situations out there every day, including the *Pharmacychecker.com* case that we cite in our brief, where courts have looked to what the established law is, including FDA regulations, and have applied that in determining whether in this case antitrust injury exists.

THE COURT: Ms. Winner, may I ask you?

MS. WINNER: Yes.

THE COURT: The cases that you've just -- I won't say "rattled off," you did that at a very good pace. But, my question to you is just whether those are the cases that you would point me to concerning -- in instances where agencies

have not taken official action, if those are the cases you would point me to in looking for authority to essentially decide that question before the agencies have spoken.

MS. WINNER: Well, I would think -- I think certainly the *Pharmacychecker.com* case would say that. I mean, whether the agency has spoken, of course, we would say the agency has spoken. The agency promulgated the regulation that we're asking to be recognized here. And since then, you know, said many things consistent with it.

You know, the *Modesto Irrigation District* case, I don't believe there was any enforcement action in that case. I don't know, you know, what the state regulatory authority may have actually said about the subject. But they have not filed an enforcement action against anyone.

There's a case -- and I'm forgetting the name. There's a case in the First Circuit that is also cited in our brief that is about somebody who did not have authority to erect billboards. There was a regulatory agency that required -- when I get up again, I'll give that you case. They had authority to -- they did not have the authority to erect billboards, because they didn't have -- they didn't have the authorization to do that. And so they couldn't sue because somebody prevented them from erecting billboards.

So, again, this was not -- there wasn't the agency coming out and making an announcement, and saying: You, you can't do

this. Although, here (Indicating), we actually do have that. It was more -- it was just the situation, that's what the law said is they needed the authority. And they didn't have the authority. And for purposes of this case, that's all that matters.

Now, the one other thing I want to say about this is the extended lives program that was cited, this was not Intuitive ignoring FDA or saying clearance isn't needed if you change the specifications of these devices.

There is a separate procedure under the law that -- where the original manufacturer can make certain kinds of changes, through an alternative procedure called the note-to-file procedure. And Intuitive thought that it was allowed to make some very minor adjustments -- mostly, I think, very minor adjustments; there may have been some that were a little more -- to some of its later-generation devices, not the ones that are at issue here, without going through the whole FDA clearance process again.

The most important thing of all of that is Intuitive was wrong about that. And FDA came in and said: No, Intuitive, you are not -- even you are not allowed to do anything to change the number of uses on one of your devices, without a completely new FDA clearance.

I'm always surprised that plaintiffs make such a big deal about that, because that is -- you know, if anything, I think

that the most clear proof of what -- how FDA feels about that. It will not allow even the original re- -- the original manufacturer of the devices to make any changes in the use limits, without a new 510(k) clearance from FDA.

Now, I'm almost out of time, so I want to talk very briefly about the market power and market definition issue.

Again, as I said earlier, I think that the -- I think Mr. Corrigan really answered it, himself, on this issue, when he asked you who you were going to believe. I mean, what he did there was he recognized that there is competing evidence on that.

On both of the -- the market definition issues he talks about -- which are precursors, by the way, to any decision about monopoly power -- they first have to determine, for example, is this MIST surgical systems robot its own relevant market, or does it compete with other forms of surgery?

We presented extensive evidence from our expert, who is a respected economist, explaining -- citing to a lot of evidence in the record, and explaining why the relevant market includes other modes of surgery as well.

They could -- the plaintiffs could have challenged his testimony on *Daubert* grounds, and they chose not to do that. They have not challenged his qualifications. They have not challenged his methodology. And, given that his testimony is admissible, and the admissibility is not contested, it, alone,

is sufficient to defeat summary judgment here.

Now, the plaintiffs may want to argue that their expert is smarter than ours, or he's more right than our expert is. Those are arguments that go to a jury. There are -- there is a raft of independent evidence, even apart from the expert testimony.

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MS. WINNER: And I would point you -- and I don't really have time to go through these slides, but you know, Dr. Smith pointed to testimony from numerous doctor witnesses, confirming the procedures they perform, sometimes with the da Vinci, or on other occasions, performed through open or laparoscopic surgery. The same thing.

(Documents displayed)

MS. WINNER: Sometimes they do it one way; sometimes they do it another way.

And this is critical. The CEO of Larkin, plaintiff Larkin, testified about how they educate their doctors on the relevant costs of these different surgical modes. So that that can be taken into account in deciding among them.

So these are economic -- this is economic competition that is going on here, in deciding how particular surgeries are to be performed.

And in fact, the former chairman of the Surgery Department at Valley Medical Center explained how relative cost can

influence which form of surgery was used.

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MS. WINNER: And, for all gallbladder surgery, they do that laparoscopically at their facility versus robotically, just because of the relative cost.

Based on that, you can't -- there -- there clearly is a disputed issue of fact here. We are not moving for summary judgment on this issue. We are not asking the Court to decide that Dr. Smith is right. But you cannot find as a matter of law that Dr. Smith is wrong.

And the same thing on the question of whether EndoWrists are a separate product. There is -- there is extensive testimony and records cited in our briefs, including from our experts relying on other evidence in the record, explaining why applying the relevant legal test, not just ad hoc statements that they pluck out of various company documents, but as -- when you apply the actual economic test that the antitrust laws look to, that this is not a separate product.

And I would also on this point -- and again, I'm out of time, but I would point Your Honor to the ***Epic Games*** decision, which is the latest from the Ninth Circuit on this and other important issues in this case. It came out in the middle of the briefing. But, it talked at some length about the test that is to be applied in determining.

And, I think I am now out of time.

MS. CAHOY: Yes, you are.

MS. WINNER: Thank you, Your Honor.

THE COURT: Thank you, Ms. Winner.

MR. CORRIGAN: Your Honor, if I could have a minute to confer with my colleague; thank you.

THE COURT: Certainly.

(Off-the-Record discussion between counsel)

MR. CORRIGAN: I'm going to do better, maybe. But if I don't, I'm going to hear it.

THE COURT: From both of us.

MR. CORRIGAN: Your Honor, Ms. Winner did not respond to anything Mr. McCaulley said. So I'm going to have the full 12 minutes that we have left on there.

Ms. Winner started by saying that -- no legal right, she mentioned that the law prohibits. And if legal right was required, we don't have it. But that's the point. The FDA has never said that. There's no indication there's a legal -- that we don't have the legal right.

She referred to, in one of her slides, the FDA statute. But if you look at Exhibit 44 in our brief, in our papers, on Page 700 and 715, that exhibit tracks.

THE COURT: You know, there's water.

MR. CORRIGAN: Um --

THE COURT: There's a water cooler there.

MR. CORRIGAN: I'll be okay, thanks.

THE COURT: Uh-huh.

MR. CORRIGAN: The language in Exhibit 44 tracks the language in that FDA statute. And they're saying: We don't need a 510(k), and this is why. And they track the language of the statutes.

Now, we also talked about the Florida cases. Very odd. In Footnote 7 in one of their briefs, they do refer to the Florida cases, but they don't cite the cases, which is an odd practice. Referring, but not citing.

And my thinking was they didn't cite the case, because they didn't want you to read it. I mean, if you read from Paragraph 8 -- Page 8, ***Rebotix*** -- I'll just read this briefly. From Judge Hernandez Covington (As read):

> "Intuitive's argument leans on what it paints as the 'undisputed fact' that 'both Rebotix and the FDA recognize that Rebotix's business of installing the Interceptor and EndoWrist require 510(k) clearance. But this issue is highly disputed.'"

They're making the same exact argument there they make here. Which is: If we keep saying it enough, it might actually be true. But it's not true. The FDA has not said that. And I spent some time on that, with my earlier slides.

Ms. Winner also talked about the ***Modesto*** case. And I'll go back to the ***Rebotix*** case, one more time. ***Rebotix*** case, on

Page 8, talks about the *Wellbutrin*, the *Canadian Import*, *Modesto*; they deal with all those cases on this legal right. And dismissed them all.

Now, also very briefly, Ms. Winner said that there's no evidence at all that Intuitive interfered with anybody getting a 510(k). But Rick Ferreira, who's the president of Iconocare, he didn't quite say to evidence, but he strongly hinted that the FDA had done a lot of different things that he had never seen before. They asked him to do a bunch of tests that made no sense, and that he strongly suspected that Intuitive had been involved in giving him a hard time on getting the 510(k). Not saying it's evidence, but he had a strong suspicion, and he talked quite a bit about it.

Now, one of the things that they do in their brief, and she did it here today, FDA, FDA, versus FDA employees. All the communications you see up there are not FDA. They're unofficial, non-binding communications from FDA.

And Ms. Winner said they're not unauthorized. That's true. They're not unauthorized. But, they're not binding. These are unofficial.

And the communications she talked about, like the one on April of 2022, that was the one that Mr. Lee walked back in July of 2022. If it was so clear and the FDA really wanted to rule on this, July of 2022 would have been a good time to do it. But they punted. That undermines all their other emails.

And I would urge the Court to take a look at the FDA -- their FDA expert Christy Foreman's report, Paragraphs 230 and 231. You'll see one more example of how they deal with the 7-22 email, which is to ignore it. Pretend it didn't happen.

THE COURT: I hear Ms. Winner saying that the FDA isn't punting, but is, instead, resting on regulation as its final word. Tell me why that's wrong.

MR. CORRIGAN: If you read the July 2022 email, they're not saying that at all. They're saying: The FDA -- I improperly used the word "decision" and therefore, you know, I might have given the mistaken...

He is walking back what he said. And they haven't been heard from since.

So the FDA has been involved in this. They have sent emails. They full-well know what's going on. They understand what these IRCs are doing. And they didn't weigh in. They've had the chance since July, and -- and after that.

THE COURT: But the IRCs backed off. Why would they -- why would the FDA need to continue corresponding with them if -- or tell me that that's incorrect, but --

MR. CORRIGAN: Well, the IRCs --

THE COURT: -- that's how I understand it. Or, at least, her presentation of it.

MR. CORRIGAN: The IRCs exited the business because they were put out of business. They didn't say, you know:

We're tired of this business. They put a lot of time and effort into this business. And ultimately, they backed off because of what Intuitive did.

So the FDA -- to say that the FDA hasn't weighed in because they backed off, it's all based on Intuitive's anti-competitive conduct. And I talked about that this morning. They didn't back out of these businesses for kicks. They spent a lot of time and effort, getting into this business.

Now whether to use laparoscopic or a da Vinci, there was a couple of slides there at the end. I'll just say, Your Honor, that in Note 7 of our first brief and Page 22 and 23 of our second brief, we deal with that.

Also, in Footnote 22 of our second brief, we deal with the issue of the fact that we did not challenge Dr. Smith on *Daubert* grounds, so it's unchallenged (Indicating quotation marks). But there are a couple cases in that footnote that show that if an expert opinion is not based on any real facts, that it's not enough to prevent summary judgment.

And in fact, Intuitive cites the *Brook* case a couple times in their brief, for that very same point. That if an expert report is not based on sufficient facts, that it's not enough to prevent summary judgment.

Now, let me just make a couple other points, Your Honor.

It is not correct that a 510(k) is required. We have no

antitrust injury. That just means that the IRC would need to get 510(k) clearance, which Iconocare did.

And second, it is not correct that if EndoWrist repair qualifies as remanufacturing, then 510(k) is required. There's a second requirement. The second requirement is whether the device is being introduced into interstate commerce for commercial distribution. So the question that Ms. Winner posed does not end the inquiry.

Another point, Your Honor, my colleagues helped me on this one. In the but-for world, we are not limited to Restore and Rebotix. They're the two IRCs that were sort of out in front.

Whether entities such as Stryker -- Stryker's a billion-dollar medical repair company. And they thought long and hard about getting into this industry as far back as 2015 and 2016. They even went so far as to sign a contract with Rebotix. They did their due diligence, and they backed off, because they didn't want to deal with Intuitive. They didn't think -- they didn't think the business was going to work out because of Intuitive's anti-competitive conduct.

So Stryker and others could get 510(k) clearance, but they chose not to do it, for fear of Intuitive's interference.

Now, one other thing I'll say, Your Honor, and this -- Ms. Winner said, and it's a footnote in their brief, that Intuitive has always been very clear, they've always been clear that they had no objection to an IRC doing repairs, if it was

pursuant to a 510(k).

And this was not in the record. It was a deposition I took pretty late.

MS. WINNER: Your Honor, I object to discussion of material that's not in the record at this point.

MR. CORRIGAN: Well, let me say this. It's certainly in the record, but it's not -- it wasn't as an exhibit for this Court -- in this motion. But it is directly responding to what Ms. Winner said.

THE COURT: Share it with Ms. Winter, please.

MR. CORRIGAN: Sure.

THE COURT: Winner, I mean.

MR. CORRIGAN: Before I tell you?

THE COURT: Yes, please.

MR. CORRIGAN: Okay.

(Off-the-Record discussion between counsel)

MS. WINNER: Well, my objection stands.

MR. CORRIGAN: This is testimony from David Ro- -- I'm sorry, Your Honor.

THE COURT: Finish your sentence.

MR. CORRIGAN: Okay. David Rosa was a high-ranking executive in Intuitive. And he was -- they submitted a declaration of his with their summary judgment papers.

Now, Rosa's declaration was dated April of this year, April of this year, with their summary judgment papers. They

cited Rosa's declaration 46 times in their 29-page brief.

And one of the things they did with his declaration is they got in this new policy statement, right? They shoveled in this new policy statement, in Rosa's declaration.

So I asked Rosa: When did you issue this statement?

"I don't know."

He didn't know when he did it. But when she says they're always clear -- and she has a footnote, they have a footnote in their brief that says were clear -- here's some Q and A that I had with Mr. Rosa at his --

THE COURT: Hold that thought.

MR. CORRIGAN: Sure.

THE COURT: You're now trying to bring in the evidence that she's objected to, and I'm still trying to just assess whether -- where -- where that fits in.

So, as I understand it, this is not something you've cited in your briefs --

MR. CORRIGAN: Correct.

THE COURT: -- to the motions for summary judgment?

MR. CORRIGAN: Correct.

THE COURT: Then I'm not going to hear it now. Since that's what this is about.

MR. CORRIGAN: Okay. This is deposition testimony from a high-ranking executive, in his deposition on his declaration that was submitted with summary judgment.

THE COURT: Ms. Winner, is your point something that was in your briefing that could have been addressed by them in some of their briefing?

MS. BASS: Absolutely, it's something, they could have -- they could have addressed it in their --

THE COURT: Then I'm going to ask you -- this should have been somewhere in their briefing already. So I'm going to uphold --

MR. CORRIGAN: Fair enough, Your Honor.

THE COURT: Sustained, sustained. We move on. All right.

MR. CORRIGAN: And let me -- if I could, could I get slide No. 22 back up?

(Document displayed)

MR. CORRIGAN: Your Honor, while we do that, let me just say that the *Kaplan* case -- they cite the *Kaplan* case several different times. The *Kaplan* case is very distinguishable.

If you take a look at Footnote 7 of the *Kaplan* case, the *Kaplan* case says: It was very important to this case that we are talking about a single-use consumable device.

Now, as you know, in this case we're not talking about that. We're talking about reusable durable devices.

Footnote 7 of the *Kaplan* case completely distinguishes that case from this. It says: We are not going to rule on any

kind of reusable device which has medical durability left after it's used once.

So in one footnote, that ***Kaplan*** case is completely divorced from this case.

(Document displayed)

MR. CORRIGAN: I will end with this one, Your Honor. This is the last slide of the deck. And the heading there is from a 1995 document:

"Number of reuses will be controlled"

And then I filled in the blanks:

"...to Protect Intuitive's Bottom Line, Not Patients."

Their senior director of regulatory affairs, a guy named Mario Lowe, he said (As read):

"Just so you know, FDA does not require nor limit the number of uses for our EndoWrist instruments."

All right?

So, why did Intuitive impose those limits? Well, here's why. 1995 foundational business plan -- this business plan is long before the FDA is even a twinkle in their eye. Intuitive would (As read):

"...derive its revenues from...high margin 'reposable' instruments which can be sterilized and reused only for the number of

times allowed by the company."

And then the kicker:

"Further, the 'number of reuses will be controlled to reflect...the gross margin and the price desired.'"

These are not about safety. These are about making money.

Now, one other thing. We cited this document, Exhibit 9, in both our briefs. They cited this document in neither of their briefs. They made no effort to distinguish or explain this document away.

And when you look at this, these three -- I'm going to do one more -- look at everything they say and do in the prism of what's on this slide.

The third one there was a 30(b)(6) witness, a guy named John McGrogan (Phonetic):

"Marketing is involved to the extent that they set [use limit] goals for engineering...

"**QUESTION:** And then engineering would try to design an instrument that would meet that 10-life goal, right?

"**ANSWER:** Yes."

We quote that in our papers. In Footnote 1 of their first brief, they say that is a false statement. That's not a false statement. That tracks their 30(b)(6) deposition testimony, directly. They say it's false, because they have nothing else

to say about it.

I think my time is up, unless Your Honor has questions. Thank you.

THE COURT: It is, it is.

And also, I see you, Ms. Winner. Go ahead.

MR. CORRIGAN: Thank you, Your Honor.

MR. MCCAULLEY: Your Honor, we are over time, but may I have one moment just to respond --

THE COURT: I want to let -- am I right to think that you want to respond just to the *Kaplan* point? Or something else?

MS. WINNER: Well, I want to respond to a number of what he said, but maybe this gentleman can go first, and then we'll --

THE COURT: All right.

MS. WINNER: I may ask for a couple extra minutes, since they've gone over time.

MR. MCCAULLEY: We are over our time, Your Honor. And I just want to respond to one question that the Court had about the FDA relying on its regulation.

And I think the 802.3(w) that Ms. Winner pointed out, that's not a requirement for 510(k). That's the definition of a remanufacturer. And the actual authority and the statutory authority comes from 21 U.S.C. Section 360, and then the Regulations 21 CFR 807.81. And that's the issue of who has to

register.

And as we pointed out in Page 15 of our opening brief, a lead FDA official makes clear that no IRCs have ever had to register under that, since that definition was promulgated. That's because FDA still hasn't said what the definition means, in 802.3(w).

What is a substantial change? That's the guidance we still haven't finalized from the FDA, that FDA has been promising and revisiting. But they haven't laid an egg on that, Your Honor. And that's the point. FDA hasn't given any guidance in terms of what constitutes a substantial change.

And so I would just refer the Court to that portion of our brief that discusses that issue.

Thank you for the extra time. I appreciate it.

THE COURT: Ms. Winner, by my count, you've got about four minutes.

MS. WINNER: I think actually I have, Your Honor --

THE COURT: If someone else has a better count, I'll take it.

MS. WINNER: Yeah, I believe I reserved ten minutes, but maybe I get --

THE COURT: No, no, I'm only counting --

MS. WINNER: I think I get about a few extra minutes, because they went over. I'm going to still try to be efficient here, Your Honor.

THE COURT: My count is the excess. I'd forgotten about the ten you reserved.

MS. WINNER: Oh. Thank you.

THE COURT: Uh-huh.

MS. WINNER: Okay.

Well, we jumped around a lot. So, let me try to go through the most significant points that I think I should respond to.

First of all, on the Florida cases, certainly there was a -- there's a suggestion that -- and I think in at least one of the decisions, it may have been the ***Rebotix*** decision -- that the FDA's view was still unclear.

But I would point out that at that point, Rebotix was still fighting with FDA. And it was unclear about whether Rebotix was going to take FDA up on its invitation to seek a -- you know, a rule, a formal ruling that it could then appeal and start an appeal process. And the Court said: Well, you know, we'll wait and see how that plays out.

The suggestion that it might affect summary judgment, depending on how FDA ruled, that was actually in the context of Intuitive's Lanham Act counterclaim, that had nothing to do with any discussion about antitrust injury, in that case.

I don't know what to make of this suggestion that Iconocare strongly suspected that Intuitive may have had something to do with the fact that it was hard to get FDA

clearance. There's certainly -- I think it's admitted, there is no evidence of that. Nobody's ever suggested that Intuitive has any control over FDA. And, sure, plenty of people at Intuitive can explain how that's definitely not the case.

But -- so I think you could -- clearly, should set that to one side.

This notion that these are all unofficial, unbinding statements, I think Your Honor really put your finger on it. You don't have to have FDA saying -- you know, making the decision every time about, you know, what -- whether the law applies in a particular circumstance.

You know, there's a law on the books that says nobody's allowed to drive more than 25 miles per hour in a school zone. That law applies to me, regardless of whether there is also a law on the books or a regulation or an official ruling (Indicating quotation marks) from some government agency that Sonya Winner can't drive her Prius more than 25 miles per hour in a school zone. The law says what it is. And the way our legal system works is that people are expected to comply with the law.

And the way the antitrust injury analysis works is that it looks at what the law says, and says that if you don't have a legal right to do something under the law, then you can't claim antitrust injury just because somebody prevented you from doing it.

Now, this statement that marketing was involved, we most certainly did respond to that. We didn't just say that it was false. What we said is that the -- we pointed to the evidence in the record which talks about how marketing was involved from Intuitive in -- in establishing use limits.

And what happened was that the clinical -- and this is the undisputed evidence in the record -- in the very, very early days when they were inventing these things and testing them and refining them and retesting them, the original use limits were even lower. And the marketing people came in and said: You've got to redo these instruments; you've got to improve them so that they'll have more uses. That was the involvement of marketing. There's nothing nefarious about that, from an antitrust perspective.

The -- the notion that FDA hasn't been heard from since they sent their favorite email or the plaintiffs' favorite email, the answer to that is very simple. There was nothing for them to be heard on -- heard on. Because there was nothing then pending.

Rebotix had the right to go forward under the process that was laid out for them. There are actually other procedures under the law that they can also follow to request a formal ruling from FDA on something. They chose not to do that. So there was nothing for FDA to do.

FDA had a regulation. FDA had been telling them for

years, you know, this regulation doesn't allow them to do what they want to do, without FDA clearance. And they decided not to go forward.

Now, finally, on the commercial distribution point. I think we addressed this fairly thoroughly in our brief, Your Honor. The *Kaplan* case is not distinguishable, based on that one footnote. If you look at -- the *Kaplan* case was analyzing: What do the words "Held for sale" mean in the statute and regulations?

They're actually interpreting language. Classic work of a court is to decide, you know: How do you interpret this language. And it's the same language we have here.

And that was a case in which a doctor had been criminally convicted of adulterating -- adulterating a device, because he used it more uses than it was allowed. That one was only allowed one use, right about that. And he -- he would dump it into some -- some disinfectant (Indicating), and use it again in his practice. And he said: Well, that's not held for sale.

And "held for sale," "held or offered for sale" is the language we're interpreting here (Indicating quotation marks). And it's the same language for the adulteration provision as it is for the provisions that we're talking about for the requirement of clearance.

And he said: Well, I don't hold -- I wasn't holding it for sale, because I didn't sell it. All I did was just use it on

my patients. And as long as I continue to own it, that's all I have to do.

Well, the Ninth Circuit said: Absolutely no way. That is not what that means in the Food, Drug, and Cosmetic Act. In the Food, Drug, and Cosmetic Act, that language applies to any activity that involves commercial use of the device. And that includes commercial use in a medical practice.

Similarly, here, we're talking about these devices being used in commercial medical practice in hospitals. Being used on patients. This isn't somebody buying a medical device and just playing with it in their basement, and never doing anything else with it. This is somebody taking a medical device, and using it on patients.

And as the Ninth Circuit made clear, the language of the Food, Drug, and Cosmetic Act, in talking about this kind of scope of where it applies, the language must be applied broadly because -- to be protective of patients.

Thank you, Your Honor.

THE COURT: Thank you, Ms. Winner.

Anyone want a seventh-inning stretch? I'm going to suggest we take one. So let's recess for a whole minute or two just to stand up and stretch. Then we will do the *Daubert* motions.

You don't have to.

(A pause in the proceedings)

THE COURT: All right, folks, we're going to get started again.

I know that I said we would move on to the *Daubert*, but I have one last question for counsel, for the motions for summary judgment. This is to any and all of you.

Is Rebotix or anyone else currently providing EndoWrist modification services?

MR. CORRIGAN: Not to our knowledge, although Iconocare does have the 510(k) on an Si instrument. So, certainly, these companies are ramping up. Certainly -- I mean, Restore and Rebotix settled their cases. They brought these cases, they litigated hard for years to get to this point. So they're now at this point when they've settled, and they are going to get back up to running. But I'm not sure if that's actually happened yet.

But, again, they litigated for years to get to this point to get back into this market. And they've taken a lot of steps to do so.

THE COURT: Ms. Winner, do you have any better knowledge?

MS. WINNER: Well, I'd love to be able to take two minutes to answer the same way. But I think, Your Honor, I would just say no.

THE COURT: Okay.

MR. CORRIGAN: Well, I'll take -- the reason they're

out of the business is because Intuitive shut them out of the business. That's why they're out of the business.

THE COURT: I very much understand that's your position. I do, I do.

MR. CORRIGAN: Thank you, Your Honor.

THE COURT: All right. Thank you both for answering the additional question.

Let's go ahead and take up the *Daubert* motion.

MS. BASS: Good afternoon, Your Honor. Ashley Bass on behalf of defendant Intuitive Surgical.

So, based off of the prior argument, obviously, Intuitive has moved for summary judgment in this case. And we believe it should be granted. To the extent it is not, we wanted to take just a few minutes to address the damages expert of the hospital plaintiffs, Professor Elhauge.

Our motion sets forth multiple grounds where we think Professor Elhauge's opinions have not meet the *Daubert* standard. We would like to focus on one fundamental flaw that means all of his damages estimates in this case are not reliable, and should be stricken.

In particular, Professor Elhauge did nothing to assess what competitive impact the third parties, like Rebotix, Restore, and SIS, would have actually had in the but-for world.

So Professor Elhauge's job in this case was to construct a world without the challenged restraints in Intuitive's

contracts. His role is to think about what would the world look like if plaintiffs won their case, and what would the damages then have been to the plaintiff hospitals and the hospitals that are in the class? We call that "the but-for world."

So he's trying to construct a world where he thinks about what would the competitive dynamics have been, and then what was the harm to the hospitals, assuming that liability was established in this case.

In assessing that but-for world, the first thing he should have thought about is what sales would these third parties have had. What hospitals were interested in using their services; how many repaired or remanufactured EndoWrists would the hospitals actually have bought from the third parties.

He actually skips this step, entirely. He makes no effort to make any sort of an assessment of what sales the third parties would have had in the but-for world.

He admitted this readily in his deposition, that he does not think about what the sales are, and he doesn't model any sort of market shares or anything of that nature for the third parties.

You might say: Well, why does this matter to a damages estimate? Well, the reason that it matters is if only a small number of hospitals are interested in using the services of the third parties, then no one would think that anyone could reach

the type of astronomical damages numbers that Professor Elhauge reaches.

He reaches those damages numbers because he posits that Intuitive would have dropped its prices by 20 percent across the board, in the but-for world. So basically what he's assuming is so long as the third parties existed, that Intuitive necessarily would have dropped its prices by 20 percent. Even though he makes no assessment of what sort of hospital or customer interest there actually was in using the devices.

Now, in the deposition that we took of Professor Elhauge, he admitted that there is obviously a relationship between -- a direct relationship between what the sales of the third parties would have been and what Intuitive's price response would have been.

So I said, in the deposition to Professor Elhauge: What if the interest in the third parties was not that great in the but-for world? What if they -- their sales were small? What if their sales were only $2 million a year? Do you think that Intuitive would have dropped its prices by 20 percent, across the board?

And he said no. Intuitive would not be motivated to drop its prices 20 percent, across the board.

That's the point. That's the question that he should have asked at the beginning of his analysis. But yet, he skipped it

entirely. He simply said so long as there was some interest in the third parties, Intuitive would have dropped all of its prices by 20 percent. He treats it like an on/off switch.

So there's at least two problems under the case law with Professor Elhauge's approach. The first is that he finds no grounding in the record.

The cases are very clear that an antitrust economic expert needs to be able to ground the damages opinion in the facts of the case. That's the holding of *McGlinchey* in the Ninth Circuit, that you can't base a damages opinion on unsupported assumptions and unsound extrapolation.

Here, Professor Elhauge didn't even make any attempt to look at what the competitive dynamics would be from these third parties. He simply ignored that step, and doesn't even tie it into the record.

The second problem is that it means that he has not offered any sort of a standardized or reliable methodology to calculate damages. All he has offered is this on/off switch approach for which he gives us no support, no academic articles, nothing to say that this is a reliable methodology.

But yet, again, cases regularly strike antitrust economic damages experts that don't set forth a reliable methodology. The cases talk about types of reliable methodologies that can be used: A regression analysis, a before-and-after approach. He uses none of those methodologies.

And that's what the Ninth Circuit *Magnetar* case says. That if you stray from an established methodology, and you don't use that when you're giving an actual antitrust damages opinion, then it is subject to being stricken.

Here, Professor Elhauge gives no support for this approach. And of course, no support could be found in law or economics for the notion that simply because a competitor exists in the but-for world, that it necessarily means that an antitrust defendant drops their prices dramatically on every product, across the board.

So what's plaintiffs response to this? They have no real answer for the fact that Professor Elhauge skipped this first step entirely. He made no analysis of it. They offer two legal arguments, in essence, for why we should just let this opinion go on to the jury.

The first is that they say: Well there could be factual disputes, and we should let the jury figure all of this out.

Well, again, the cases are very clear that what you need is a sufficient factual foundation in the record before you can submit the damages opinion to the jury. That's what the *Marion* case (Phonetic) says; that's what the *Voucher* case says.

Then they say: Well, there's some leeway in thinking about what damages would have been, because we don't know what would have happened in the but-for world; we're constructing a world that never existed.

And there are cases that talk about that leeway. But the Ninth Circuit is very clear that the speculation and guesswork cannot be the basis of an antitrust damages opinion that goes to the jury. Again, that's *McGlinchey*, and that is *Magnetar*. There has to be a reliable basis for that opinion to get before the jury, especially when we're talking about the astronomical damages that are at issue here.

So the bottom line here, the conclusion is that Professor Elhauge, to boil it down, has said: Well, I think that there was sufficient interest in these third parties that Intuitive necessarily would have dropped its prices on all EndoWrists by 20 percent.

He offers us no methodology to reach that. He doesn't tell us what shares or what sales he thinks the third parties would have made. He gives us his say-so. That is not a recognized methodology. And it's not a reliable methodology.

Certainly, if the third parties would have sold 5 percent, that's something that he could have said. Maybe he thinks they'll sell 50 percent. We don't know. We don't know what he thinks that the third parties would have necessarily sold, in terms of remanufactured EndoWrists.

And there's a big difference between whether they would have sold 5 percent or whether they would have sold 50 percent, as to what Intuitive's price response would be. He skips that step, that infects his whole analysis, and all of his damages

start from the premise that is absolutely unreliable.

Now, with the Court's indulgence, I would like to point out one other piece that we did not get to in the summary judgment argument, but that overlaps with the arguments that we made in the *Daubert* as to Professor Elhauge. And that's with respect to damages on the X and Xi.

We moved, on *Daubert* grounds, on Professor Elhauge, to say that he doesn't have a reliable basis to estimate damages for the X and Xi EndoWrists because no company has commercialized a process to reset those EndoWrists. He generates a substantial amount of damages based off of his X/Xi reset EndoWrists. So the X/Xi EndoWrists were introduced in 2014. We stand here today, no one has commercialized a process in order to reset those EndoWrists.

Now, in plaintiffs' presentation today, you saw them refer to the testimony of Mr. Hamilton as if that answered all the questions. So with the Court's indulgence I'm going to read the surrounding Q and As with respect to Mr. Hamilton, because I think once you read the Q and As in context that actually answers the question.

Here's the question to Mr. Hamilton, of Rebotix (As read):

> **"QUESTION:** What is missing from the process? What is missing from the process to fully develop and implement the ability to reset the usage of Xi EndoWrist instruments?

"**ANSWER:** Final procedures, testing, validation, same things we had to go through for the Si. All the testing that has to be done, and is now in progress. But it takes time.

"**QUESTION:** I want to make sure I understand your testimony. Are you saying that from a technical standpoint, Rebotix has actually reset the usage counter of an Xi EndoWrist, as of today?

"**ANSWER:** I'm not sure how you're defining that. Have we done it in the marketplace? I said no. Have we done the technical equivalent of that, I said yes. And there are many steps between the technical equivalent and releasing it into the marketplace."

The bottom line, as we stand here today, nobody has commercialized an X/Xi reset, and there's no basis for Professor Elhauge to generate substantial damages numbers, based off of the X/Xi EndoWrists. Thank you, Your Honor.

THE COURT: Ms. Bass, before you take your seat, am I right, you -- neither of you are reserving time for rebuttal. So I have one question for you before you go, which is: Could you please address why it's insufficient for you all to simply

cross-examine Mr. Elhauge, to impeach his conclusions.

MS. BASS: Absolutely. And that's why I wanted to talk about -- both about the cases that talk about the sufficient factual basis. Those cases specifically say that that is not an issue just, then, to reserve to the jury. If there's not a factual foundation, then you should not simply submit it to the jury to sort it out.

That is an issue both -- like I said, in *Marion* and *Voucher*, that specific question was asked. The plaintiff argued: Let's just submit this to the jury; surely there's a fact question there.

And the court said: No. What *Daubert* requires is a sufficient factual foundation in the record before we would submit that to the jury. And if that factual foundation is lacking, then that isn't simply an issue of cross; it's an issue of not having the foundation for the jury even to hear the testimony.

And then relatedly, the second part of that is the reliable methodology. Again, the jury -- you know, they are not economists. Professor Elhauge is a law professor, and he is offering an economic opinion here. And in terms of what he needs to offer to the jury, it has to have a reliable methodological basis before it's allowed to go to the jury.

And again, that is what the cases like *Magnetar* and like *McGlinchey* say. That in the Ninth Circuit, we're going to make

sure that before we put something before the jury, that it really has that reliable basis to it.

And the Court that I think really best summarized this issue was *Toscano*. And what the Court in *Toscano* said -- it's a District Court here in California. It says it's (As read):

> "...not a prescription for the antitrust plaintiff to shirk his responsibility to present competent and probative evidence from which a jury can reasonably determine damages."

So again, without that factual underpinning, without that reliable methodology, then the issue should never reach the jury.

THE COURT: Thank you.

MS. BASS: Thank you.

MR. BATEMAN: Good afternoon, Your Honor. Chris Bateman for the hospital plaintiffs.

The purpose of Rule 702 and *Daubert* is to screen out expert opinions that are nothing more than "nonsense" or "junk science," as the courts have put it. Not to take up judicial resources generally litigating the merits of expert opinions.

Yet, the latter is exactly what Intuitive has done with the 11 *Daubert* motions that it has brought against all ten plaintiff experts across these two cases. These are meritless blunderbuss motions that ignore the liberal standard favoring

admissibility of expert testimony as the Supreme Court and Ninth Circuit have put it.

And this is evident with Intuitive's motion to exclude Professor Elhauge's opinions, including his damages estimates, and the motion that it has chosen to prioritize here.

And I'll focus on, you know, what Ms. Bass focused on in her comments here largely about the damages estimates. As noted in our brief, courts have described Professor Elhauge as an antitrust titan, and have found him qualified to opine on economic issues in antitrust cases in all 22 cases in which he's been the subject of a *Daubert* motion.

His damages estimates here are based on standard methodologies that are routinely used and upheld in antitrust cases, including yardstick comparisons, and reliance on defendants' own business plans and documents.

And here, the latter is particularly helpful, as Intuitive, itself, planned out its own response to the threat of rival EndoWrist repair in the form of Project Dragon, its planned instrument refurbishment program, and the extended-use program, the plan that it actually adopted to extend the uses on certain EndoWrists, in the face of even just limited competition.

Intuitive doesn't argue that Professor Elhauge is unqualified. And they effectively concede that the damages methodologies he uses are commonly accepted. They just quibble

with the details of those estimates, and their factual, you know, basis, raising what are essentially fact disputes that Your Honor is exactly correct are properly the stuff of cross-examination, and not exclusion.

And to focus on the issue that Ms. Bass first discussed with the modeling of but-for market share, this is a perfect example of Professor Elhauge's methodologies and how they are commonly accepted and valid. Professor Elhauge -- it's true he didn't model, himself, the but-for market shares that the repair companies would achieve in a but-for world. He didn't need to do that. Intuitive and others did it for him.

Professor Elhauge draws in his reports on Intuitive's own projections that EndoWrist repair could obtain substantial market share. At least 10 to 15 percent, according to Intuitive's own documents.

And similar projections by Deutsch Bank and by Stryker, the major medical supply company that was discussed earlier, and that planned to enter the EndoWrist repair market by purchasing Rebotix, but was deterred only by Intuitive's restraints when it turned those up in its due diligence. And those projections are consistent with and, indeed, based on the very robust demand for EndoWrist repair that's clear from the record, and that Professor Elhauge also cites extensively in his reports.

And then the Project Dragon evidence, then, shows

Intuitive was planning to respond to that predicted threat with 20 to 40 percent price discounts. So Intuitive, itself, thoroughly gamed out both the threat and the response here, making it unnecessary for Professor Elhauge to do additional modeling like that, himself.

And that's an example of that -- one of those valid, commonly-recognized methodologies. Reliance on the defendant's own documents, the defendant's own projections, which the ***ZF Meritor*** case (Phonetic) that we cite recognizes as a valid methodology. And the ***Blood Reagents*** case also cites.

So, so that criticism, you know, simply fails. Professor Elhauge does have a sufficient factual foundation for those analyses. And, you know, any questions about the -- you know, those projections are kind of questions that should be left for cross-examination and for a jury, under ***Daubert***.

And, you know, his analyses are -- in those respects are completely different from the expert opinions that were excluded in the ***McGlinchey*** case, for example, where one of the two experts was the plaintiff, himself. And he, you know, was not an economist, and he didn't even document his own projections. And there were clear factual problems with his analyses that were just, you know, fundamental. Including, for example, saying that there were -- you know, taking the gross sales, and extrapolating from gross sales, the plaintiffs' own gross sales what the damages would be, when it was only just a

subset of those sales that were affected by the defendant's anti-competitive conduct. And the expert wasn't even familiar with what that anti-competitive conduct really was, and what effect it had on the plaintiffs' business, as the expert, himself, admitted in a deposition, if you read that opinion.

And we talk about Professor Elhauge's reliance on the projections done by Intuitive and by Stryker and Deutsch Bank in Footnote 10 of our opposition brief.

So it's not true, also, just to revisit one point that she made there, that Professor Elhauge simply treats it as an on/off switch, and as long as there's some tiny amount of demand, you get all these damages. That's not what Professor Elhauge was saying. He made that clear in his deposition, in fact. He, you know, made clear that he was relying on the projections made by these third parties, and that he didn't need to model these things, himself, because Intuitive, itself, again, gamed out the -- you know, the predictions of market share, and then gamed out its own response very specifically with these 20 to 40 percent price discounts, for example.

And so in his deposition, he testified about that at Pages 207 to 208. And also Pages 280 to 281.

As for the X/Xi damages, so, Ms. Bass, you know, focused on the claim that no company has fully commercialized the process for repairing these X/Xi instruments and resetting their use counter. But we saw the evidence earlier from Stan

Hamilton of Rebotix, testifying that Rebotix has figured out how to overcome what is the real key, you know, technical impediment here, the real, the real obstacle to actually entering into this market, which is resetting the use counter. He clearly testified that they have done that.

And he's not the only one to testify that this is feasible. Restore's Cliff Parker, for example, testified he was 100 percent confident that Restore would be able to do the same. Restore's Kevin May testified that he was highly confident that Restore would be able to get around the X/Xi use counter.

And Professor Elhauge cites all this evidence at Paragraph 275 of his opening report. Similarly, he also cites Rebotix's engineering firm that it hired in 2016 to analyze this very question of whether it was possible to get around the Xi use counter, the same engineering firm that it hired for -- to consult on the X/Xi use counter, which they did successfully circumvent. And this engineering firm concluded that it should be feasible to do this. So Professor Elhauge cites that too.

Finally, he also cites the expert opinion of SIS's cryptography expert, Kurt Humphrey, testifying that it should be, you know, possible; it would have been feasible at any point in the last five years to get around the X/Xi use counter.

So given all of that testimony about the feasibility of

doing this, the fact that Rebotix has overcome the key obstacle to doing it, and then the other evidence that Professor Elhauge cites, and economic principles, and namely the obvious one that's the large economics incentive to enter this market -- you know, we're talking about hundreds of millions of dollars in possible business, you know, from repairing these X/Xi EndoWrists. So given all that, and the evidence that the repair companies, including Rebotix and Restore, long planned to enter this market but were deterred by Intuitive's restraints -- and by "this market" I mean the X/Xi EndoWrists part. And Professor Elhauge cites that evidence at Paragraph 263 of his opening report and Paragraph 416 of his rebuttal report.

Given all of this, Professor Elhauge has a reliable basis to offer this as a reasonable scenario to just present it to the jury as a reasonable damages scenario. He's not saying that this necessarily would have happened in the but-for world. He's just saying that there's sufficient evidence to conclude that it would have been possible. And that it's a reasonable damages estimate to present to the factfinder.

Thank you, Your Honor. If there are any questions I can answer about this motion, I'm happy to.

THE COURT: No.

Counsel, I want to thank you all for your presentations today. I will take all of these motions under submission. I

have -- oh, go ahead.

MS. WINNER: Your Honor, I just wanted to say I had promised Your Honor to identify a particular First Circuit case.

THE COURT: That's right.

MS. WINNER: Without argument, I just tell you the case I was referring to is the *RSA Media Inc*. case in the First Circuit. It is 260 F.3d, 10.

THE COURT: Thank you, Ms. Winner.

I have just one more matter for all of you before we adjourn. I want to speak with you all about calls placed this morning to the Clerk's office about getting your materials in to the courthouse today. That call was placed to the main line downstairs.

That person, the person who called, didn't have the case number handy, didn't know which judge was in charge of the case, and just kept referring to me as "the Latina judge" in trying to get the materials here.

There are three things I want to say to all of you about that, and about my expectations for you all going forward.

First: Inquiries about getting materials to the courthouse should not happen the day of the hearing. I want all of those to please happen the day before at the latest. And I appreciate tremendously that you all emailed -- I don't even know how long ago because it feels so long ago -- about

how this hearing would run. I appreciate you all doing things with enough time. So that's the first point. Calls the day of should not happen.

Those queries should not go down to the main clerk. They go -- they are best directed to my CRD, Ms. Solorzano -- you all have her email address, it's available on my website, it's available all over the place on the Court's website -- because she is, in fact, the best point of contact for anything related to how to get materials in front of me.

And third: No one should be calling this Court without a case number and without knowing something more about the matter. You are wasting the time of the folks in the Clerk's office. And it isn't appreciated.

So I just want to make sure to say that to all of you. Because I anticipate we'll see -- we may be continuing to do this for some time. And I would like for none of this to repeat again.

Thank you again. You'll hear from us. I wish you well. Safe travels home.

MR. CORRIGAN: Thank you, Your Honor.

THE COURTROOM DEPUTY: This calendar is now concluded.

(Proceedings concluded)

CERTIFICATE OF REPORTER

I, BELLE BALL, Official Reporter for the United States Court, Northern District of California, hereby certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/ Belle Ball

Belle Ball, CSR 8785, CRR, RDR

Sunday, September 10, 2023